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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-18,22-25,28-30 and 34 is/are rejected.
- 7) ☒ Claim(s) 20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 04/25/05.

Claims 1, 2, 7-18, 20-25, 28-30 and 34 are pending.

Claim Rejections - 35 USC § 103

1. Claims 1, 2, 7-18, 22, 23, 28-30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with

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Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors. The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph,

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right column, page 139). A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where Founderguard supplements the feed for treating stereotypic behavior in animals. Johnson and Winskill clearly teach the method of the instant claims except that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior and with the expectation that the histamine type-2 antagonists or proton pump inhibitor will reduce or inhibit gastric secretion leading to treatment of stereotypy or cribbing.

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2. Claims 24 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and “timothy hay” (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse’s inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill’s study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by

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Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teaching of Winskill, Pagan and Johnson. One having ordinary skill in the art would have been motivated to include the antacid of Johnson or Pagan in the feed of Winskill as feed for horses and the modified composition would be expected to reduce hindgut acidity or control the pH of the hindgut and thus minimize the incidence of stereotypy in horses.

3. Claims 20 and 21 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20 and 21 are directed to including fat and fiber and optionally antacid to the animals diet from birth or including the fiber diet in the feed of the lactating mother and the cited prior art is silent on feeding lactating mothers and horses from birth with a diet of fat, fiber and antacid.

Arguments

Applicants argue:

a) That the examiner miscalculated the percent fiber and fat for the Winskill reference; applicants state that when converted properly, the fiber comes in at 20% and the fat at 2.75; applicants conclude therefore, that the amounts are outside the range specified by claim 1. Furthermore, applicants argue that fat and fiber are not critical to alleviating stereotypic behavior in Winskill, while both the fiber and fat are critical in alleviating stereotypic behavior in the present claims.

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b) That Johnson discusses link between hindgut acidity and stereotypy and hindgut acidity is different from stomach acidity; combining the Founderguard of Johnson with the composition of Winskill would not produce a composition that is within the scope of claim 1 because Founderguard is not a stomach antacid.

c) That the pH changes in the GI tract, namely, from acidic stomach to alkaline small intestine to neutral/acidic hindgut, and as such the hindgut acidity can only be lowered by caecal infusion and not by oral administration since oral administration of sodium bicarbonate as indicated by the examiner would not survive the acidic stomach as the bicarbonate would be neutralized by the acidic stomach. Therefore, one of ordinary skill in the art would not orally administer sodium bicarbonate since the bicarbonate would be neutralized before reaching the hindgut; and though caecal administration of sodium bicarbonate would be effective for hindgut acidity reduction, would not have any effect on stomach acidity. There is therefore no motivation for the person of ordinary skill to use sodium bicarbonate as a stomach antacid.

Therefore, the combination of Winskill and Johnson fails to teach a method of treating stereotypy by reducing stomach acidity. Pagan fails to remedy the deficiencies of both Winskill and Johnson because Johnson is related to treating equine gastric ulcers.

d) That Winskill does not recognize that administration of fat and fiber composition is effective in treating animal behavior; that Examiner fails to appreciate the difference between hindgut acidity and stomach acidity and that Johnson fails to link stomach ulcer formation with stereotypy; that Pagan does not recognize the impact of treating equine ulcers on behavior.

Response to Arguments

4. Applicants' arguments filed 04/25/05 have been fully considered but they are not persuasive.

Regarding a), Examiner thanks applicants for correctly calculating the percent amounts of fiber and fat relative to the total weight of the food/feed. It is however noted that 20% fiber intersects a point on the fiber curve/range of from about 15% to about 70%. 2.75% fat is lower than the about 5% minimum in the fat recited in the claim 1. It is also noted that instant claim 1 is a composition claim and future intended use is not critical in a composition claim. Generally, differences in amounts of the disintegration agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There is no demonstration that a composition comprising about 2.75% fat and 20% fiber would not alleviate stereotypic behavior in the presence of an antacid. There is no demonstration of unusual or unexpected results from fiber that is chopped and a demonstration showing that fiber that is not chopped would be ineffective in alleviating stereotypy in the presence of antacid. Although future intended use is not critical in a composition claim, instant claim 1 states that it is the combination of fat, fiber and antacid that is useful in treating or ameliorating animal stereotypy and claim 11, which is a method claim, says that controlling stomach pH of an animal minimizes or ameliorates or treats animal stereotypy. Thus, applicants' assertion that fat

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and fiber are critical to alleviating stereotypy appears not to reflect the method claim 11 and also the composition claim 1.

Regarding b), Johnson is relied upon for a disclosure of feed/food containing antacid that lowers incidence of stereotypy in horses. The goal of Winskill is to reduce stereotypy or increase foraging in horses and Winskill's feed composition though containing no antacid was effective in combination with football to increase foraging time and thus lowered stereotypy. Thus a third composition can be formulated from the combination of Winskill and Johnson as a feed for horses and the motivation of including the antacid of Johnson is produce a feed that would be expected to lower the incidence of stereotypy. Thus, without considering the future intended use of claim 1, the combination of Winskill and Johnson produces a food composition that is within the scope of instant claim 1. Also, the combined teaching of Winskill and Johnson is within the scope of the claim 1 even when the future intended use is called into play.

Regarding c), it is noted that claim 1 recites antacid, and sodium bicarbonate meets the generic antacid limitation. The method claim 11 administers stomach antacid to an animal and the administration of the antacid does not exclude oral administration. Sodium bicarbonate is also a stomach antacid (abstract of JP 02069421 as a teaching reference). As discussed above, there is an expectation of success that stereotypy in the horses will be lowered when an antacid is included in the composition of Winskill. Johnson discloses controlling acidity in horses/equine. Pagan discloses neutralizing acidity in equine with histamine type-2 antagonists and equine antacid. Since bicarbonate and histamine type-2 antagonists and equine antacid control acidity in the horse/equine, it is prima facie obvious to substitute one antacid for the other and expect to

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produce the same effect of acidity control. Therefore, a combination of Pagan with Winskill and Johnson is proper.

Regarding d), it is noted that Winskill discloses the relationship of foraging and stereotypy and feed composition of fat (oil) and fiber combined with football activity. However, the instant claim 1 is a composition that comprises antacid, fiber and oil; and instant claim 11 administers antacid to lower or minimize or ameliorate or treat animal stereotypy. The claims do not state that stereotypy is lowered or minimized or ameliorated by administering fiber and oil composition and thus the argument that Winskill does not recognize that fiber and oil composition is effective in treating stereotypy is not within the scope of the examined claims. Thus the references taken together disclose the composition of the instant claims and discloses also the method of the instant claims. Therefore, the combination is proper. Acidity is related to pH and controlling the pH is also controlling acidity or pH.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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